



PHARMACY COUNCIL OF THE GAMBIA
No. 112 Kairaba Avenue
Fajara , KMC
Tel: 4495572 or 769 0904 or 738 26 55, P.O.Box 4527 Bakau



Website: www.gpc.gm

Guideline for Licensing of Premises

PCG-GL-201, Version 1.0 – 15 January 2020

Table of Contents

1	List of Abbreviations and Acronyms.....	3
2	Introduction	3
2.1	Legal Basis.....	3
2.2	Purpose and Scope.....	3
3	General Requirements	3
4	Application for New Licensing	4
5	Application for ReNewal of Licenses.....	4
6	Issueing of a License.....	5
7	Final Provisions	5
8	References.....	5
9	Document History	5
10	Flow Chart: New Licensing	6
	Annex 1: Minimum Staffing and Supervision Requirements	7
	Annex 2: Location of Premises.....	8

1 LIST OF ABBREVIATIONS AND ACRONYMS

NMC	Nursing & Midwives Council of The Gambia
PCG	Pharmacy Council of The Gambia
SOP	Standard Operating Procedure

2 INTRODUCTION

2.1 Legal Basis

- 2.1.1. The regulation of licensing of premises in The Gambia from which medicines are supplied, sold or dispensed is governed by the provisions and requirements of the Pharmacy Council Act, 2014, by which the Pharmacy Council of The Gambia (PCG) was established as the regulatory body for the practice of pharmacy.
- 2.1.2. Part VI Section 21 – 23 and Part V Section 24 stipulate the requirements and conditions for licensing of premises.
- 2.1.3. The Pharmacy Regulations 2018 detail the legal requirements with respect to premises, personnel, activities and fees.
- 2.1.4. The Standards of Pharmacy Practice in The Gambia published by the Pharmacy Council sets the standards in the various practice areas.

2.2 Purpose and Scope

- 2.2.1. This guideline describes the application and procedures for new licensing of premises where medicines are sold, supplied, dispensed or compounded, and for the renewal of premise licenses.
- 2.2.2. It applies to wholesale pharmacy businesses, retail pharmacies (community pharmacies), public and private health institutions including hospitals and clinics that provide pharmacy services, veterinary clinics and drug store outlets. Supermarkets need to have a permit from the PCG to sell medicines.
- 2.2.3. The licensing of premises by the Council shall ensure that the premise is suitable for the supply of medicines.

3 GENERAL REQUIREMENTS

- 3.1. The PCG provide licenses for the following Pharmaceutical Outlets:
 - Wholesale
 - Health institution including Hospital/Clinic Pharmacy
 - Community Pharmacy
 - Drugstore
 - Veterinary Drugstore
- 3.2. The PCG provide a permit to Supermarkets to sell medicines.
- 3.3. Each license covers only a single premise.
- 3.4. A license by the PCG will only be granted, if a supervisor responsible for the premise is registered with the PCG. In case of veterinary drugstores

supervisor shall be registered with the Veterinary Council. Nurse dispensers shall also be registered with the Nursing and Midwives Council (NMC).

- 3.5. A premise license by the PCG will only be issued when the proposed location of the premise, premise conditions and personnel comply with the Act and the Regulations. The PCG may apply other regulation of the distribution of pharmacies in The Gambia.
- 3.6. The PCG charges non-refundable Premises License Fees for new licenses and renewals as specified in the Schedule of the Regulations. The fee is due at the time of submission of an application.
- 3.7. All premise license holders must be resident in The Gambia.

4 APPLICATION FOR NEW LICENSING

- 4.1. For the license of a premise (or in case of supermarkets a permit) the Premise Licensing Application Form must be completed by the applicant. The application form is available from the PCG website: www.gpc.gm.
- 4.2. The following documents must be submitted with the application:
 - a) Copy of National Identity Card or Passport for identification;
 - b) Copy of Business registration;
 - c) Copy of Tax Identification (TIN);
 - d) Copy of the Supervisor's current Registration certificate with the respective Council; and
 - e) Copies of certificates of other personnel.
- 4.3. Any other additional documents might be requested by PCG.
- 4.4. The documents must be written in English. If the original is written in another language, a certified translation must be provided.
- 4.5. The PCG inspectorate will contact the applicant for a suitable date to meet for an assessment visit and will make recommendations as appropriate. If possible, this visit should take place at the premise.
- 4.6. The applicant is required to respond within 45 days following the assessment visit and inform the PCG about the implementation plan of the recommendations by the inspectors, if any.
- 4.7. After a timely response, the inspectors conduct an inspection of the premise before a license can be granted to verify the suitability of the premise and the adherence to regulatory requirements (for details, refer to the PCG Guideline for Inspections of Premises).

5 APPLICATION FOR RENEWAL OF LICENSES

- 5.1. The premise license (or in case of supermarkets a permit) must be renewed every year before 31st March of the ensuing year.
- 5.2. For the renewal of a license the Premise Licensing Application Form must be completed by the applicant. The application form is available from the PCG website: www.gpc.gm.

- 5.3. The following documents must be submitted with the application:
- a) Copy of the previous year's license;
 - b) Copy of the Supervisor's current Registration certificate with the respective Council; and
 - c) Copies of certificates of other personnel.
- 5.4. Any other additional documents might be requested by PCG.
- 5.5. In case of any changes since the last year this must be declared in the application form.
- 5.6. The PCG inspectorate may visit the premise for inspection before renewal of the license (for details, refer to the PCG Guideline for Inspections of Premises).

6 ISSUEING OF A LICENSE

- 6.1. In case of new licenses, if all requirements are met, the licence will be issued within one month after the approval following the inspection visit.
- 6.2. In case of renewals within one month after reception of the valid application.
- 6.3. The license will stipulate the business to be carried out on the premise, the name and registration number of the supervisor and the expiry date.
- 6.4. A wholesale license pharmacy business cannot be issued a license for retail.
- 6.5. The original license must be displayed in the premise.
- 6.6. Planned changes in Supervisor, location or name of premise must be communicated to the PCG immediately. The PCG will consider and approve the request at least six (6) months from date of receipt of the request. For the relocation request or change of Supervisor from an urban to a rural settlement, the request may be granted immediately.

7 FINAL PROVISIONS

- 7.1. This guideline is the first version. It will become effective on 15 January 2020 and be published on the PCG website.
- 7.2. The document will be reviewed within 3 years of becoming effective.

8 REFERENCES

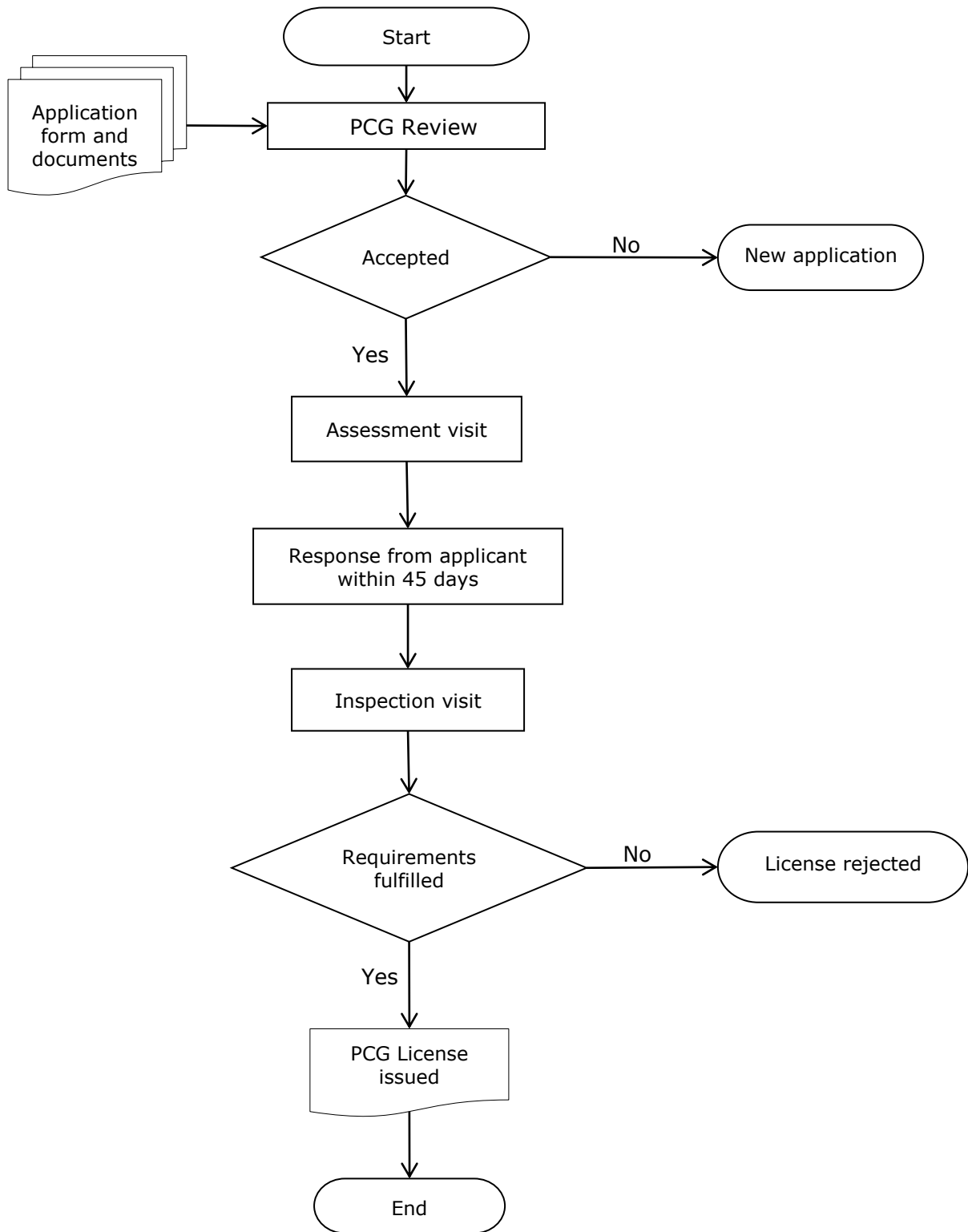
- Pharmacy Council Act, 2014
- Pharmacy Regulations 2018
- Standards of Pharmacy Practice in The Gambia (PCG-GL-301)
- Guideline for Inspection of Premises (PCG-GL-302)

9 DOCUMENT HISTORY

Version:	Issue Date:	Reasons for Change:
-----------------	--------------------	----------------------------

1.0	15 January 2020	New document
-----	-----------------	--------------

10 FLOW CHART: NEW LICENSING



ANNEX 1: MINIMUM STAFFING AND SUPERVISION REQUIREMENTS

Table 1: Staffing

	Wholesale Outlet	Retail Pharmacy	Retail Drugstore
Pharmacist	1	1	/
Pharmacy Technician/ Nurse Dispenser	1	2	1
Dispensing Assistant	1	2	/

Table 2: Supervision

	Pharmacist	Pharmacy Technician/ Nurse Dispenser
Wholesale Outlet operating \geq 10 hours	2 hours/day	/
Retail Pharmacy operating \geq 14 hours	4 hours/day	/
Retail Drugstore operating \geq 14 hours	/	10 hours/day

Note: A pharmacist may supervise not more than one (1) wholesale and two (2) retail pharmacies at a time.

Table 3: Staffing of Health Facilities

	Minor Health Centre	Major Health Centre	General Hospital	Specialist/ Teaching Hospital
Pharmacist	/	1	2	14
Pharmacy Technician/ Nurse Dispenser	1	3	8	15
Dispensing Assistant	3	5	10	/

ANNEX 2: LOCATION OF PREMISES

The minimum distance from mass transit points to a retail pharmacy or drugstore and from a pharmacy or drugstore to another pharmacy or drugstore distance shall be 200 metres.

Mass Transit Points are:

- Banjul Albert Market Area
- Westfield Junction Area
- Serrekunda Market Area
- Brusubi Roundabout ('Turntable') Area
- Brikama Market Area
- Soma Market Area
- Basse Market Area
- Farafeni Market Area

For the rest of the communities the minimum distance from a Pharmacy or Drugstore to another pharmacy or drugstore shall be 500 metres and from a pharmacy or drugstore to a public health facility including hospitals and clinics 200 metres.